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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,837	08/26/2003	Robert J. Sweeney	279.648US1	3849

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/648,837

Applicant(s)

SWEENEY ET AL.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33,35,36,38 and 40-46 is/are rejected.
- 7) ☒ Claim(s) 34,37,39,47 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-6 and 16-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Siegel (U.S. Patent No. 5,062,841).**

Siegel teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swallowable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel also teaches that the swallowable member swells in response to an increase in blood glucose level (col. 3 lines 51-56). In regards to claims 1 and 2, Examiner takes the position that the hydrogel membrane as taught by Siegel has at least one physical property (swelling) that changes in response to a physiological condition (an increase in blood glucose level). Further, Examiner takes the position that change in size due to swelling, is inherently detectable by use of acoustic energy.

In regards to claims 3-6, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-33 and 35 stand rejected**, and claims 36, 38, and 40-46 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,296,630) in view of Lew et al. (U.S. 2003/0100822), and further in view of Siegel (U.S. Patent No. 5,062,841) as applied above.

Altman et al. teaches of an implantable cardiac drug delivery system for delivery agents to be introduced within the myocardium of a subject (col. 9 lines 32-35), comprising a delivery patch or patches that may consist of a hydrogel (col. 12 lines 11-13), a catheter (col. 7 lines 56-61), and the use of an acoustic transmitter (col. 20 lines 39-43). The Altman et al. reference does not specifically teach that hydrogels are commonly known in the art to be pH and/or ion sensitive, nor does the Altman et al. reference teach that hydrogels are commonly known in the art to swell in response to a physiological condition.

Lew et al. teaches that hydrogels, including pH sensitive hydrogels, are well known in the art for being used as protective biocompatible coating for implantable devices, and are further defined as polymeric materials that swell in water and other fluids (paragraphs 7 and 9).

Siegel teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swellaable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel also teaches that the swellaable member swells in response to an increase in blood glucose level (col. 3 lines 51-56).

In regards to claim 1, Examiner takes the position that hydrogel membrane that makes of the patch as taught by Altman et al. would be inherently capable of having at least one physical property change (swelling in size) in response to a physiological condition, such as an increase in blood glucose level since it is known that hydrogels have the characteristic, as taught by Siegel (col. 3 lines 51-56).

In regards to claims 3-6 and 22-29, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size. In the alternative, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Altman et al. to include hydrogels that are capable of swelling as taught by both Lew et al. and Siegel, since the hydrogels as taught by both Lew et al. and Siegel are well known in the art for being biocompatible membranes.

In regards to claims 8, 18 and 30, Examiner takes the position that implantable membrane could be of any shape, including spherical, and would be a matter of design choice. In regards to claims 18, Altman et al. teaches that of the use of multiple patches (70 and 75) that have membranes, which may comprise a hydrogel (col. 12 lines 11-13).

In regards to 12-15, Examiner takes the position that the Altman et al. reference inherently teaches of the use of a display, user interface and an external programmer, since the ultrasound transducer is being used in connection with ultrasound imaging (col. 20 lines 39-42). Examiner also takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system to include use of a computer network in connection with the user interface, since it is well known in the art to use a network for enhanced feedback and communication of detected results.

Further in regards to claim 19, the limitations of the claim are clearly anticipated by Lew et al. in the Abstract, as well as Figures 2, 11, 16 and 17.

Regarding claim 38, Altman et al. discloses a body sized and shaped to be introduced within a vein or artery (column 9, lines 55-66; column 11, lines 24-39).

Regarding claims 40 and 43, an implantable medical device including a state that is altered using a change in the physical property is disclosed both by Siegel (ABSTRACT) and by Lew et al. (ABSTRACT, where the hydrogel is considered the IMD which alters its size in response to the change in analyte concentration adjacent to it).

Regarding claims 41 and 42, Let et al. discloses a controller circuit coupled to the acoustic receiver (paragraph [109]) and an external interface configured to receive information (Figs. 2 and 11).

Regarding claims 36, 44 and 45, Altman et al. discloses an implantable medical device including an intravascular lead with an acoustic transducer (column 27, lines 13-44).

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Regarding claim 46, Siegel discloses modifying a therapy using the detected change in the physiological condition (ABSTRACT).

Allowable Subject Matter

5. Claims 34, 37, 39, 47 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

6. Applicant's arguments, see paragraph 2 of page 9, filed 17 July 2006, with respect to the rejection of claim 36 under 35 U.S.C. §112 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the previously applied references.

7. Applicant's arguments filed 17 July 2006 with respect to the rejection of claims 1-6 and 16-17 under 35 U.S.C. §102(b) as being anticipated by Siegel have been fully considered but they are not persuasive. Claims 1-6 and 16-17 stand rejected for the arguments made of record in the Office Action filed 18 April 2006 and restated in paragraph 2 above.

Applicant argues that Siegel fails to disclose that the swellable member changes to an extent such that it is capable of being detected by acoustic energy. Applicant maintains the position that the change in size due to swelling will inherently be

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detectable by the use of acoustic energy, such as medical ultrasound in the range of 10-15MHz which provides high axial and lateral resolution. It is also a reasonable assertion that ultrasound will be able to detect said changes through a housing.

Furthermore, in view of the apparatus claims, it is not necessary for the prior art to expressly disclose a limitation such as the one being argued, but rather need only be *capable of* producing said result. Since it is held that the disclosure of Siegel provides a member capable of swelling to a size detectable by acoustic energy, the rejection under 35 U.S.C. §102(b) is deemed proper.

8. Applicant's arguments filed 17 July 2006 with respect to the rejection of claims 1-33 and 35 as being unpatentable over Altman et al. v. Lew et al., f.i.v. Siegel have been fully considered but they are not persuasive. Claims 1-33 and 35 stand rejected for the arguments made of record in the Office Action filed 18 April 2006 and restated in paragraph 4 above.

Applicant argues that none of Altman, Lew or Siegel discloses a swellable member that will change to an extent that would be capable of being detected by acoustic energy with adequate signal-to-noise ratio. Examiner maintains that this is identically the function of the device disclosed in the Lew et al. reference (ABSTRACT; Figs. 2, 11, 16,17). Applicant also argues that Altman does not indicate locating a hydrogel within a myocardium. However, this is explicitly stated in the cited portions of the reference, so no further explanation is deemed necessary. Furthermore, even if such a feature were not disclosed, the device of the rejecting reference need only be

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capable of locating a hydrogel within a myocardium. It is held that Altman, Lew, and Siegel are all capable of such a location for the swellable member.

Regarding Applicant's arguments toward claim 19, as worded the claim is clearly anticipated by the Lew et al. reference as outlined above in paragraph 4.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

26 January 2007


George Manuel
Primary Examiner